

**REMARKS**

This Amendment is responsive to the Office Action dated September 2, 2004.

In that Action, the Examiner required Applicant to submit a new Declaration and Substitute Specification for the application. Applicant is enclosing herewith as Exhibit A an executed Declaration and Power Of Attorney respectfully believed to be in compliance with at statutory laws and regulations. Applicant is also enclosing a substitute specification for the application. A marked up version of the substitute specification is attached as Exhibit B and a clean version of the substitute specification is attached as Exhibit C.

By this Amendment Applicant specifically submits that it is entitled to small entity status.

Original claims 1 and 2 were objected to and rejected under Section 112, second paragraph. Original claims 1 and 2 were also rejected under Section 102(b) in view of the Edwards patent.

Claims 1 and 2 have been cancelled without prejudice. Claims 3-22 have been added. No new matter has been inserted. Claims 3-22 remain pending in the application. Applicant respectfully requests reconsideration of the Examiner's rejection and the citation of the Edwards patent.

The Edwards patent relates to a Spirometer Apparatus which is a different apparatus than the Incentive Spirometer device disclosed and claimed by Applicant. A Spirometer is used prior to surgery (such as in a doctor's office) to test the health of the patient's lungs. A Spirometer Apparatus is used for performing "substantially instantaneous" breathing flowrates tests such as Forced Expiration Volumes (FEV). The process of Forced Expiration Volumes (FEV), which is only one breathing procedure of the Spirometer. However, as taught by Edwards, all procedure require substantial instantaneous breathing airflow for function, which

is done quickly for exhalation and inhalation flowrates performed by the patient to test the strength of the lungs when airflow is breathe therethrough the Spirometer Apparatus. The substantially instantaneous breathing requirement process is taught throughout the Edwards patent as the sole breathing performance. Applicant's claimed Incentive Spirometer device is not used for performing the substantially instantaneous breathing process or any other breathing procedures required by the Edwards disclosure. The Edwards Spirometer Apparatus is not used or disclosed by Edwards for performing sustained maximal inspiration (SMI) process, which is the claimed intended use of Applicant's claimed Incentive Spirometer device.

An Incentive Spirometer device is used after an operation as a postoperative device to rebuild the lungs after a surgery, as the lungs are deflated during surgery. An Incentive Spirometer device can only be used for "inhalation" under the specific SMI breathing requirements as taught by the American Association for respiratory Care. As mentioned above, the SMI breathing requirements are not taught or disclosed by the Edwards patent. However, they are taught by the ATS (American Thoracic Society) and AARC (American Association for Respiratory Care), as the only proper therapy for the use of the Incentive Spirometer device is the SMI (sustained maximal inspiration) procedure.

An Incentive Spirometer device is used to perform sustained maximal inspiration (SMI) procedures, which are defined as the therapeutic performance of exclusively inhalation therapy, requiring slow sustained deep breaths. The SMI procedure is required for rebuilding the lungs after an operation and reestablishing the patient's normal pulmonary hyperinflation. The Edwards patent does not teach this principle or requirement, which is only specific to the Incentive Spirometer device (SMI). An Incentive Spirometer device cannot be used for exhalation as

it could harm the patient. Accordingly, it should be recognized that an Incentive Spirometer device (Applicant's claimed invention) is a completely different device than a Spirometer apparatus (Edwards) and that they are used for completely different purposes.

Even in a hospital setting the Edwards Spirometer is used as a test for continuous breathing monitoring where the patient has pneumonia, Emphysema and/or other lung illnesses. A Spirometer apparatus, including the Edwards Spirometer, is not used for postoperative rebuilding of the lungs through deep breathing SMI. The SMI procedure is only performed with an Incentive Spirometer device which is the type of device improved by Applicant's claimed invention. Applicant is not improving a Spirometer (Edwards).

Applicant's claimed Incentive Spirometer device is used primarily for a postoperative patient staying in a hospital. By continuously prompting and enticing the patient to use the Incentive Spirometer device, the patient is more likely to use the Incentive Spirometer device, which in turn speeds up the patient's recovery. Furthermore, the claimed Incentive Spirometer device continues to send prompting verbal messages to the patient until the patient performs the sustained maximal inspiration (SMI) procedure. This claimed feature further increases the usage of the Incentive Spirometer device, as the device continues to nag the patient until it is used. Edwards fails to disclose or teach this claimed feature. Furthermore, given the nature of use of a Spirometer (Edwards), there is no need or advantage to provide a prompting component to the Edwards device.

Additionally, Edwards only provides verbal instructions on how to use a Spirometer. Applicant is not claiming providing verbal messages on how to use an Incentive Spirometer device. Rather, Applicant is sending verbal messages to a patient (user),

which prompts or encourages the patient to pick up the device and use it. Applicant's claimed verbal messages can also send encouragement messages to the user based on a result achieved by the user in performing SMI with the Incentive Spirometer device. Again these claimed messages are not teaching a user on how to operate an Incentive Spirometer device. Rather, Applicant's claimed messages encourage or prompt the user in order to increase usage of the device by the user. Additionally, by verbally indicating to the user what the measurement is from performing an SMI procedure with the Incentive Spirometer device, Applicant's device can be used by a user who is blind or has trouble seeing.

Edwards also fails to disclose or teach Applicant's unique conductive configuration for obtaining measurement readings from performance of the SMI procedure by the user with the Incentive Spirometer device. Edwards also fails to disclose or teach providing verbal encouragement messages to the user based on the read measurements.

As the Edwards device is intended to be used by more than one person it requires a filtration system, whereas the Applicant's invention is a single-use device. Additionally, a rotor blade assembly, requiring pitch adjustments and periodic calibration, is used for obtaining FEV measurements. Applicant's claimed float type Incentive Spirometer device is known for its disposable nature after the patient is finish with device for its intended SMI purpose. No filtration or sterilization systems are needed with Applicant's device. Furthermore, the rotor blade configuration is structurally and functionally different than Applicant's claimed conductive element configuration.

Edwards' rotor blade is used for measuring FVC (forced vital capacity), FEV (forced expiration volume), PEF (peak expiration flow) and MVV (maximum voluntary ventilation). Edwards is silent

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regarding SMI the procedure performed with the claimed Incentive Spirometer device.

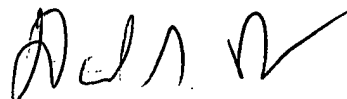
In addition to being a Spirometer and not an Incentive Spirometer, Edwards also fails to teach of a means for preventing messages from being transmitted under certain conditions as claimed by Applicant, which can be a photosensor or deactivation key. As mentioned above, Edwards does not provide encouragement or prompting messages and merely provides instructions on how to use the Spirometer. However, there is no means for preventing associated with the Edwards instructions.

In view of the above, Applicant respectfully requests that the Examiner withdraw the citation of Edwards against the claims of the patent.

Applicant has completely responded to the Office Action dated September 2, 2004. Favorable action is respectfully requested.

If there are any additional charges, including extension of time, please bill our Deposit Account No. 503180.

Respectfully submitted,



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